Xuri T Cell Expansion Medium

CELL CULTURE

Rapid cell proliferation for faster manufacturing

Effective treatments in cell-based immunotherapy are dependent on sufficient cells being administered to patients along an urgent timeline. Xuri™ T Cell Expansion Medium is optimized for rapid and reliable growth of human T lymphocytes in static culture as well as in bioreactor expansion and does not contain phenol red or antibiotics. Developed for use in GMP environments, the convenient bag format incorporates medical grade PVC tubing enabling sterile-connection to Xuri Cellbag™ bioreactors (Cytiva) thereby preserving the integrity of your functionally closed system.

Under the same conditions in a 14 day expansion protocol (1), Xuri T Cell Expansion Medium can provide the same cell count as X-Vivo™ 15 (Lonza) up to three days earlier (Fig 2). By enabling elevated rates of proliferation of viable human T lymphocytes (Fig 3) to high cell densities, Xuri T Cell Expansion Medium provides more flexibility with cultivation time even when dealing with difficult cells to start with due to donor variation.

Minimize variability for consistent performance

Reproducible and reliable performance is essential in the regulated field of cell therapy manufacturing. Xuri T Cell Expansion Medium is manufactured under a strict quality management system and the fully validated production process ensures extremely high levels of consistency between batches (Fig 4). This gives you more control over achieving the cell numbers you need and one less uncertainty to worry about.

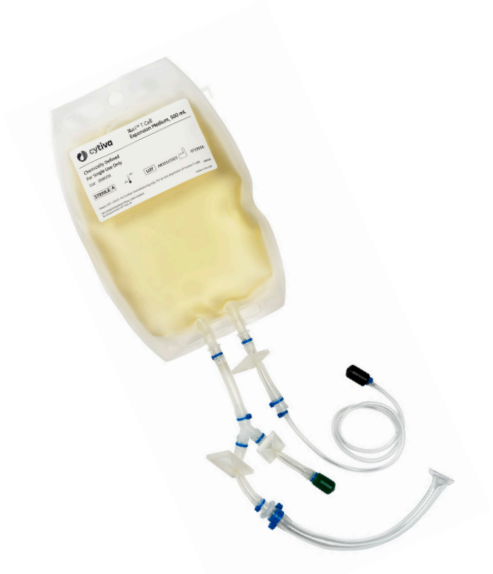

Fig 1. Xuri T Cell Expansion Medium is supplied in bags that can be easily connected to a Xuri Cellbag bioreactor.

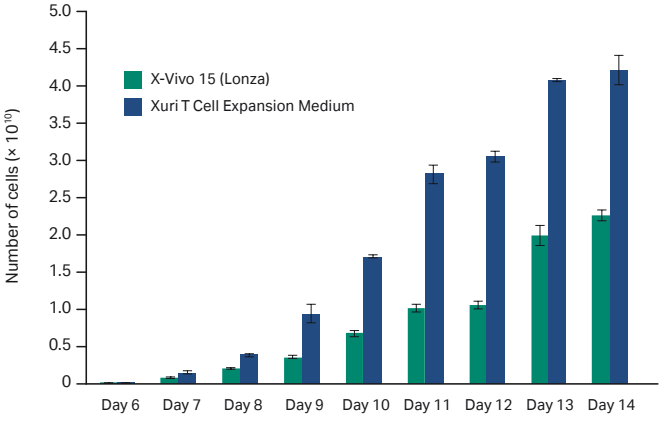

Fig 2. T cells isolated from peripheral blood were cultivated in each media with 5% human serum plus 350 IU/ml Xuri IL-2. Cells were cultivated in triplicates under static, fed-batch conditions until day 6 to grow to at least the minimum cell count necessary for seeding (> 5 × 10^8 cells) of the bioreactor. All cells were then transferred and cultivated on a Xuri Cell Expansion System for an additional 8 days under perfusion. Data shown as mean with standard deviation (N = 3). Cell viability at end of experiments for all sets was ≥ 90%. Percentage of CD3-, CD4- and CD8-positive cells were comparable in all experiments (data not shown). Experiments were conducted by Cytiva at The Maynard Centre, Cardiff, UK during August and September 2016.

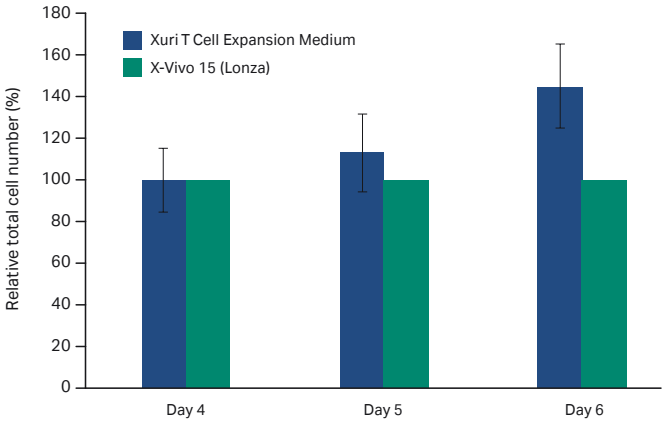

Fig 3. T cells isolated from peripheral blood of three different donors were cultivated in each media in static culture with 5% human serum plus 350 IU/mL Xuri IL-2. Data shown as the relative total cell number (%) in Xuri T Cell Expansion Medium against cells cultivated in X-Vivo 15 (100%) under fed-batch culture conditions in T flasks as mean of three donors with standard deviation (N = 3). Percentage of CD3-, CD4- and CD8-positive cells were comparable in all experiments (data not shown). Experiments were conducted by Cytiva at The Maynard Centre, Cardiff, UK during August and September 2016.

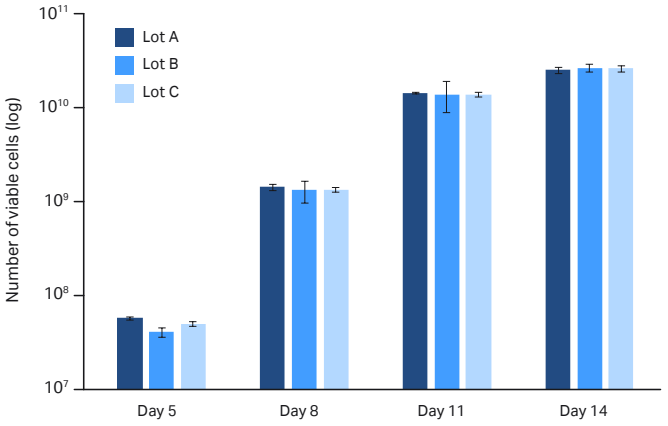

Fig 4. T cells isolated from peripheral blood were cultivated in three different manufacturing lots (A, B, and C) of Xuri T Cell Expansion Medium with 5% human serum plus 350 IU/mL Xuri IL-2. Data shown as the total cell number from fed-batch culture conditions in T flasks (day 5) to perfusion in Xuri Cell Expansion bioreactor (days 8, 11, and 14) as mean of triplicates for each of the three different lots with standard deviation in Log scale (N = 3).

Reduce risk with a functionally closed system

Developed as part of an integrated system to support the needs of cell therapy manufacturing, Xuri T Cell Expansion Medium is supplied in bags designed for attachment to Xuri Cellbag bioreactors used with the Xuri Cell Expansion System. Each bag includes a single medical grade PVC tube fitted with a male Luer lock and a C-Flex™ tube fitted with a female Luer. The PVC tubing can be sterile-welded to tubing from a Xuri Cellbag bioreactor and the C-Flex tubing enables injection of additional supplements such as human serum and IL-2 through the port into the medium prior to use.

USP <1043> compliance

A smooth regulatory submission process is key when dealing with cell therapy requirements. To help users assess and document their production processes, a comprehensive customer regulatory support file that follows USP <1043> requirements on ancillary material for cell, gene and tissue-engineered products is provided*. Further information can be received from our Regulatory Support Web Application at www.cytiva.com or our Regulatory Customer Support team at RegulatorySupportPS@cytiva.com.

A supplier you can trust

Cytiva is a global organization with a long history in bioprocessing. We are committed to developing high quality products that will provide consistent and reliable performance in cell therapy applications. Our quality management systems meet the supplier requirements of USP<1043> and conform to ISO13485 standards to make sure you can use the product with reduced risk assessment in your GMP facility. We provide a compendium of product documentation to support customer validation and offer direct contact and support from our highly qualified and experienced Customer Support team whenever it is needed.

* Xuri T Cell Expansion Medium meets USP <1043> "ancillary materials for cell, gene, and tissue-engineered products", within the responsibilities applicable to a supplier. Other aspects of USP <1043> will be the responsibility of the end-user to assess. Cytiva cannot fulfil USP <1043> in regards to application and therapy specific aspects (e.g., use in finished therapeutic, assessment of removal from a finished therapeutic and possibly biocompatibility, cytotoxicity or adventitious agent testing).

Ordering information

Description	Pack size	Product code
Xuri T Cell Expansion Medium	500 mL	29185230
Xuri T Cell Expansion Medium	1 L	29185231

References

1. Protocol: T cell expansion with Xuri systems, Cytiva, 29112375 Edition AB (2016). (Online www.cytiva.com/xuri)

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